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Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fisher's Lane, Room 11-44  
Rockville, MD 20857

Re: Serzone  
FDA Docket No. 95E-0038

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,338,317 issued July 6, 1982. The application was filed on January 20, 1995, under Title II of Public Law 98 - 417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. 156(d)(2)(A).

Gerald A. Dost  
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Office of the Deputy Assistant Commissioner  
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cc: Richard P. Ryan  
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